REMARKS

Claims 11-15 presently appear in this case. No claims have been allowed. The official action of May 2, 2007, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for treating an individual suffering from multiple sclerosis by administering to such individual an A3 adenosine receptor agonist.

The examiner has objected to the abstract of the disclosure because it does not meet the requirement of the MPEP for U.S. applications. A complete revision of the content of the abstract has been required on a separate sheet.

The abstract has now been amended in order to obviate this objection.

The examiner states that the application was filed with informal drawings. The examiner suggests that the figure be edited for clarity of printing in black and white.

Attached hereto is a new page of Fig. 1 that is in black and white. It is requested that this page be accepted as the formal drawing in this case.

The examiner states that the present disclosure fails to include "cross-references to related applications" as is allegedly required by 37 CFR 1.78 and MPEP 201.11. This requirement is respectfully traversed.

The examiner's attention is invited to 37 CFR 1.78(a)(2)(iii), which states that reference to related applications must either be included in an application data sheet or the specification must contain or be amended to contain such reference in the first sentence following the title. See also § III of MPEP 201.11, which says the same thing. It is sufficient that all of the specific references to prior applications be in an application data sheet. The examiner's attention is drawn to the fact that an application data sheet containing the appropriate references was filed on January 13, 2005. Reconsideration and withdrawal of this requirement is therefore respectfully urged.

Claims 11-15 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The examiner states that the instant claims are directed to the treatment of multiple sclerosis, but the instant disclosure has failed to produce any teaching or experimental data wherein this particular disease or condition has been shown to be effectively treated by any compounds specifically or generically disclosed herein. Therefore, the examiner considers the written description to be inadequately supportive of the instant claimed subject matter. This rejection is respectfully traversed.

The examiner's attention is invited to page 1, lines 11-13, of the present specification, which states:

> Experimental autoimmune encephalomyelitis (EAE) is the commonly used animal model for

> MS. It may be induced in wild-type animals such as rodents by inoculation, or appear spontaneously in genetically susceptible strains.

In support if this statement, submitted herewith are the following three articles:

1. Gold R, Hartung HP, and Toyka KV, "Animal models for autoimmune demyelinating disorders of the nervous system," *Mol Med Today*, 2000 Feb;6(2):88-91 - see pages 88-90.
2. Link H and Xiao BG, "Rat models as tool to develop new immunotherapies," *Immunol Rev.*, 2001 Dec;184:117-28 - see pages 117-119 and 125.
3. Mix, E., Pahnke, J. and Ibrahim, S.M., "Gene-expression profiling of experimental autoimmune encephalomyelitis," *Neurochemical Research*, 2002 Oct;27:1157-1163 - see abstract and introduction.

As those of ordinary skill in the art understand that EAE is a proven animal model for testing the effectiveness of drugs for treating MS, the asserted therapeutic utility for the treatment of MS would be accepted by those of ordinary skill in the art. In other words, an animal model example in a specification constitutes a working example for the claimed treatment of a disease, as long as the animal model correlates with the disclosed or claimed method invention. See MPEP 2164.02. The EAE animal model correlates with the treatment of MS, as this model is recognized as correlating thereto.

Accordingly, reconsideration and withdrawal of this rejection is therefore respectfully urged.

Claims 1-15 have been rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for the treatment of EAE, does not reasonably provide enablement for the treatment of MS. This rejection is respectfully traversed.

As indicated above, it is well accepted by those of ordinary skill in the art that the animal model of EAE correlates to MS. The publications cited above and submitted herewith further establish this point. Accordingly, those of ordinary skill in the art would know how to use the present invention for the treatment of MS and would believe that it would be useful in this regard in view of its success in treating EAE as conceded by the examiner. Accordingly, reconsideration and withdrawal of this rejection are also respectfully urged.

Claims 13 and 14 have been objected to because there is a mixing of two Markush formats, both of which are acceptable. The examiner has requested that only a single format be used in the interest of clarity.

While applicant disagrees that the claims were unclear, nevertheless they have now been amended to consistently use the "or" format. Accordingly, this objection has now been obviated.

Claims 11-13 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the term "adenosine

A3 receptor agonist." The examiner considers this term to be generic and not defined by any particular chemical structure or structures, thereby rendering the metes and bounds of the instant claim indefinite. This rejection is respectfully traversed.

The term "adenosine A3 receptor agonist" is a well known art recognized term. See, for example, the patents mentioned in the first paragraph on page 4 of the present specification. See also the claims of patent 7,064,112 of the present inventor, where this term was accepted as a valid generic term, the meaning being well understood to those of ordinary skill in the art. In view of the well known meaning of this term, reconsideration and withdrawal of this rejection are respectfully urged.

The examiner states that in claim 13, at line 38, the term "wherein, when R_4 is hydrogen then" appears to be a proviso. Applicant has been requested to introduce the word "proviso" to make clear that the scope of the claim is being limited by the subsequent paragraph. The examiner states that the same is true with respect to line 49 of claim 13.

Claim 13 has now been amended as suggested by the examiner, thus obviating this rejection. It should be noted that the reference to "Z" at the end of the claim is intended to be part of the proviso.

Claims 11-12 have been rejected under 35 U.S.C. 102(b), as being anticipated by Chan. This rejection is respectfully traversed.

Chan does not anticipate because the compounds disclosed in Chan are A_{2a} antagonists. At column 3, lines 13-16, Chan explicitly says that the compounds of that invention generally lack agonist activity of the human A_3 receptor and may even possess antagonist activity at the human A_3 receptor. As all the present claims require use of an adenosine A_3 receptor agonist and as Chan explicitly states that his compounds are not A_3 agonists and may even possess antagonist activity, Chan cannot be considered to anticipate. Reconsideration and withdrawal of this rejection are therefore respectfully urged.

Claims 11 and 12 have been rejected under 35 U.S.C. 102(b) as being anticipated by Castelhano. The examiner refers to page 8 and claims 39 and 42. This rejection is respectfully traversed.

The examiner's attention is invited to the abstract of Castelhano, which states that the compounds thereof specifically inhibit the adenosine A_3 receptor. A compound that inhibits a receptor is not an agonist but an antagonist. See paragraph [0103] of Castelhano. Thus, as Castelhano teaches only adenosine receptor antagonists, it cannot anticipate either of claims 11 or 12, which require use of an adenosine A_3 receptor agonist. Reconsideration and withdrawal of this rejection are therefore respectfully urged.

Claims 11-12 have been rejected under 35 U.S.C. 102(a) or (b), as being anticipated by Dolezal. the examiner refers to page 69, structural formula "I" and to page 97,

claim 9, wherein the instant claims are allegedly anticipated. This rejection is respectfully traversed.

Dolezal is not available as a reference as it was published on July 15, 2004, which is after applicant's priority date. As the priority document is in the English language, the examiner can ascertain that the present claims are supported by the priority application and are therefore entitled to an effective filing date of December 29, 2003. Thus, Dolezal is not a reference under either 35 U.S.C. 102(a) or 102(b). Furthermore, nowhere does Dolezal state that the disclosed compounds are A_3 adenosine receptor agonists. In addition, formula I (page 69) has an additional methyl group attached to the ribose, which is missing in the present formula (IV). Accordingly, reconsideration and withdrawal of this rejection are also respectfully urged.

It is noted, with appreciation, that the examiner has indicated that claims 13-15 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112, and to include all of the limitation of the base claim and any intervening claims. However, in view of the fact that claims 11 and 12 have been shown to be allowable hereinabove, it is not necessary to rewrite claims 13-15 in independent form at the present time.

It is submitted that all of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. 112. Reconsideration and allowance and therefore earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By /rlb/
Roger L. Browdy
Registration No. 25,618

RLB:jmd
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
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